Comments from PM
Short Term Studies

1) Spell out BM names fully 1st time used in Synopsis and in body of CSR.
   a) Use abbreviation thereafter.

2) Synopsis will including: *only* key Results, Discussion, and Conclusions from the body of the report.
   a) Very succinct, minimal narrative, bulleted lists (or tables??) whenever possible.

3) The word treatment must be in quotations (e.g., "Treatment").
   a) It is preferred to use this only when another term, such as Group, is inadequate.

4) Capitalize Acclimation, Baseline Day, and Day 1, etc.
   a) Use EITHER "per day" or "per 24h" CONSISTENTLY.

5) Present comparisons between Groups in standardized order; always group of interest 1st (e.g., PREP).

   a) Do NOT use terms such as "original data values" unless unavoidable.
   b) Do not use "data Type 1 (or 2, 3, 4)".
   c) Give exact units and name for the biomarker of interest.
   d) Tables for BM adjusted for cpd should read: *BM adj for number of cigs smoked per day (BM mass/cig) or Mean BM adj for number of cigs smoked per day versus study day by treatment (% change from Baseline).*
      i) NOT *Mean BM versus study day by treatment (% change from Baseline adj for number of cigs smoked per day).*

6) Adjust *ONLY* 24h urine biomarkers of exposure for cpd.
   a) CLARIFICATION: units are ng/mL per cig
   b) DELETE 8-epi-PGF$_{2a}$, 11-DHT, urine albumin adjusted for number of cigs smoked per day (correlation w/ cpd scientifically valid ONLY for BOE at this point).
   c) EVERY BIOMARKER TABLE/FIGURE TITLE/AXIS SHOULD STATE THE BM UNITS USED (e.g., mass/day, mass/cig).
      i) *ALL* should have a numerator *AND* a denominator (e.g., usually mass/day or mass/cig).
   d) Correct units for NE are mg/day and mg/cig. Need *urine* before *albumin* (always, including TOC Table titles).

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7) For regression analyses, *only* Day -1 and Day 8 are important.

   a) Present R^2 and slope of <u>statistically significant</u> relationships.

   b) Use R^2 and not R2. If there are statis signif correlations:

8) Questionnaire analysis:

   a) *Fagerstrom Test for Nicotine Dependence* is correct nomenclature.

9) *ELIMINATE* THE TERMS "DOSE" (e.g., Table 14.3.1.1), PREDOSE, POSTDOSE, DRUG.

10) The Conclusions in the Synopsis should include all the collated Conclusions from the body of the report.

11) Use past **tense** consistently throughout. Active **voice** is preferred to passive.

12) Post-text order of BMs (for Tables, Figures, Appendices) should match that in-text, and should be BOE, then BED, then BOPH as follow:

   a) BOE: NE, Cotinine, NNAL, 3-HPMA, S-PMA, 1-OHP, mutagenicity

   b) BED: $COHb\ AUC_{(7-23)}$ *(this is the actual BM in this study, not COHb itself)*

   c) BOPH: Triglycerides, HDL-C, LDL-C, fibrinogen, hs-CRP, total bilirubin, 8-*epi*-PGF_{2a}, 11-dehydro-TxB_2, urine albumin.

13) Be certain that all trademark symbols are superscripts.

14) Always, italicize *epi, trans, cis, S-, N-, O-*..

15) Never capitalize *epi-, trans-, cis-*, hs (as in high-sensitivity). This means that, when one of these begins a bullet or sentence, in which the first word should be capitalized, instead capitalize the NEXT word (e.g., 8-*epi*-Prostaglandin..., 11-Dehydro-thromboxane...).

16) In the List of Abbreviations, be consistent in capitalizing the first word in the abbreviations.

17) Add a dictionary of terms that defines: nicotine equivalents; biomarker of exposure; biomarker of potential harm; biomarker of effective dose; potential-reduced exposure product, vital signs, hematology; controlled; smoking topography.

18) Center all in-text tables.

19) Be consistent with the spelling of Fagerstrom or Fagerström.

20) Present "mean±sd" rather than mean/sd.

21) Use abbreviations for chemicals following their first appearance in the text.

22) Replace "restricted" with "controlled" and "unrestricted" with "uncontrolled".

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23) Indicate multiplication by an "x", e.g., ppm x hr.

24) Replace "nicotine and its five metabolites" with "nicotine equivalents".

25) Use "subject" (not "patient").

26) Use "adult smokers" (not "smokers").

27) Use "in-house study" or "controlled, in-house study" (not "confinement study").

28) Use singular "Week" when used as an adjective for the noun "visit" (e.g., Week 2, 4, 6, and 12 visits), but plural "Weeks" when used as a noun (e.g., at Weeks 2, 4, 6, and 12).

29) Spell out state names (e.g., Virginia instead of VA).

30) Be consistent in EITHER spelling out OR using numerals for numbers < 12 (e.g., 7 instead of seven). I prefer we use numerals.

31) Use military time instead of civilian time (e.g., 01:30 instead of 1:30 a.m., 23:00 instead of 11:00 p.m.).

32) Italicize *e.g.,* and *i.e..*

33) Use high-sensitivity CRP or hs-CRP (not HS-CRP).

34) Nicotine, cotinine, *trans-3'*-hydroxycotinine, and NNAL listed by name alone without "free" or "total" descriptors implies the free biomarker (excludes any conjugated portion). *Since most of these compounds exist in the free form, the deconjugation step is not routinely done unless specified.*

35) Use "total 1-OHP" (not 1-OHP).

36) Use "particulate phase", "gas phase" or "gas/vapor phase" (no hyphens in U.S. English, only British English).

37) Use tobacco smoke "constituents" (not "components").

38) Use cigarette "delivery" (not "yield").

39) In the CSR (Volume 1), give full descriptive stats (N, mean, SD, median, range, 95% CI) for EACH **biomarker** in the post-text tables.

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40) Send *one* sturdily-bound **hard copy** of the ENTIRE draft CSR (EVERYTHING that's on the CD-ROM) with the electronic copy.

41) Include in Volume 1 of the CSR: a comprehensive **Table of Contents** that includes all TOC for Volume 1 AND for all subsequent individual Volumes of the CSR. On both the electronic copy and hard copy (spine and cover), prominently number each volume as *<Volume x of xx>* where xx represents the final volume of the CSR (e.g., Volume 10 of 37).

42) **Lists of Abbreviations, Definitions,** and **Calculations:** Include any terms with a specific meaning for THAT study that may be misinterpreted by the reader if the intended meaning is not defined (e.g., controlled smoking; unrestricted smoking; residual effect; nicotine equivalents). Repeat any study-specific **calculations** in the data analysis section (e.g., for nicotine equivalents, residual effect adjustments).

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